REMARKS

The Office Action of September 26, 2003, has been received and reviewed. Applicants would like to thank the Examiner for the courtesy extended in the interview of March 25, 2004. Claims 1-36 are pending in the application. Claims 1, 2, 8-11, 22, 23, 26-33, 35 and 36 stand rejected and claims 3-7, 12-21, 24, 25 and 34 have been withdrawn from consideration as being directed to a non-elected invention. Claims 1, 8, 22, 27, 29, 33, and 35-36 have been amended and claims 2, 10-11, 23, 26, 28, and 30-32 have been canceled as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is requested.

Oath/Declaration

The oath or declaration was thought to be defective. A supplemental declaration is submitted herewith.

Specification

A substitute specification, without claims, was requested since it was thought that the amendment filed 9/12/00 was too extensive to be entered into the specification. Although the amendments to the specification filed in the amendment of 9/12/00 were in compliance with the rules, a substitute specification is submitted herewith as requested by the Examiner.

Claim Objections

Claims 27-32 were objected to under 37 CFR § 1.75(c) as assertedly being of improper dependent form for failing to further limit the subject matter of a previous claim. It was thought that claims 27-32 attempt to further define the claims on which they depend by use or administration elements. Claims 28 and 30-32 have been canceled rendering the objections thereto moot.

Claims 27 and 29 have been amended as set forth herein in order to comply with 37 CFR § 1.75(c). For instance, claims 27 and 29 have been amended to depend from claim 1.

Withdrawal of the objections of claims 27 and 29 is requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-2, 8-11, 22-23, 26-33 and 35-36

Claims 1-2, 8-11, 22-23, 26-33 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Claims 2, 10-11, 23, 26, 28 and 30-32 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein.

Specifically, it was thought that the claims are drawn to a genus of compounds (and a genus of using them) that is defined only by their function and that in order to provide adequate written description, the specification must provide sufficient distinguishing characteristics of the genus of the inhibitor. (*See*, Office Action at page 4). Although applicants do not agree that any of the claims lack compliance with the written description requirement, to expedite prosecution, claim 1 has been amended as set forth herein.

As amended, independent claim 1 is directed to a method for reducing binding of a ubiquitin-proteasome system to a cell surface receptor, the method comprising: contacting a cell with a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx (SEQ ID NO: 1), wherein D is aspartic acid, E is glutamic acid, F is phenylalanine, I is isoleucine and x is any other amino acid, wherein said peptide corresponds to the motif of SEQ ID NO: 1; thus reducing the incidence of the ubiquitin-proteasome system binding to the cell surface receptor. Since the method of claim 1 is directed to a specific peptide, *i.e.*, a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx (SEQ ID NO: 1) and wherein said peptide corresponds to the motif of SEQ ID NO: 1, one of ordinary skill in the art would conclude that the inventors had possession of claim 1.

Support for the amendments to claim 1 is found, *inter alia*, at pages 9-11 of the as-filed specification. Specific support for xEFIxxDx is found, *inter alia*, at page 9, lines 11-28 and Table I of the as-filed specification. For instance, Table I lists peptides that correspond to the

motif xEFIxxDx, wherein the peptides of Table I that correlate to the motif xEFIxxDx have varying amino acids at the residues indicated with "x." Further, it is known in the art that the one letter designation "x" refers to any amino acid. Submitted herewith are printouts from www.ncbi.nlm.nih.gov evidencing that "x" is known to represent any amino acid. Thus, one of ordinary skill in would understand that the inventors had possession of amended claim 1.

Claims 8, 9, 22, 27, 29, 33, and 35-36 should comply with the written description requirement as they depend from independent claim 1.

Reconsideration and withdrawal of the written description rejections of claims 1, 8, 9, 22, 27, 29, 33, and 35-36 are requested.

Claims 1-2, 8-11, 22-23, 26-33 and 35-36

Claims 1-2, 8-11, 22-23, 26-33 and 35-36 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Claims 2, 10-11, 23, 26, 28, and 30-32 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as hereinafter set forth.

As amended, independent claim 1 is directed to a method for reducing binding of a ubiquitin-proteasome system to a cell surface receptor, the method comprising: contacting a cell with a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx (SEQ ID NO: 1), wherein D is aspartic acid, E is glutamic acid, F is phenylalanine, I is isoleucine and x is any other amino acid, wherein said peptide corresponds to the motif of SEQ ID NO: 1; thus reducing the incidence of the ubiquitin-proteasome system binding to the cell surface receptor.

"As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable relation to the entire scope of the claim, then the enablement requirement is satisfied." (M.P.E.P. § 2161.01(b), *citing In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA)). Further, enablement may be established as long as "the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice

it without an undue amount of experimentation. (*Id.* at § 2164.02, *citing In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Claim 1 is directed to a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx. The specification discloses that the ubiquitin-proteasome binding site comprises xEFIxxDx (*See*, Specification as-filed, page 9, lines 11-20). Once a binding domain is known, one of ordinary skill in the art would be able to use a system such as, for example, a PEPSCAN system in order to find a peptide that binds to the binding domain. (*See generally*, *Id.* at page 10, line 34 through page 11, line 24). Thus, claim 1 should be considered to be enabled.

Claims 8, 9, 22, 27, 29, 33, and 35-36 should be enabled as depending from claim 1.

Accordingly, reconsideration and withdrawal of the enablement rejections of claims 1, 8, 9, 22, 27, 29, 33, and 35-36 are requested.

Claims 26-33

Claims 26-33 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the claimed invention. Claims 26 and 30-32 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein.

Claims 27-29 and 33 have been amended to depend from the method of claim 1, wherein the recitation of "pharmaceutical composition" has been removed from claims 27-29 and 33.

Reconsideration and withdrawal of the enablement rejections of claims 27-29 and 33 are requested.

Rejections under 35 U.S.C. § 102

Claims 1-2 and 8-9 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Fenteany *et al.* (U.S. Pat. 5,756,764) and under 35 U.S.C. § 102(b) as assertedly being anticipated by Lee *et al.* Claim 2 has been canceled rendering the rejection thereof moot. Applicants respectfully traverse the rejections as set forth herein.

Since Fenteany *et al.* and Lee *et al.* do not disclose each and every element of claim 1, it cannot be anticipated. For instance, Fenteany *et al.* does not disclose a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx as recited in claim 1. Fenteany *et al.* is limited to "compounds structurally related to lactacystin and lactacystin β-lactone" and does not disclose the use of any peptide. (Fenteany et al., Col. 1, lines 44-45).

With regard to Lee *et al.*, it also does not disclose a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising xEFIxxDx as recited in claim 1. Lee *et al.* is limited to use of the proteasome inhibitors listed in the Experimental Procedures section of the paper, none of which are peptides. (*See*, Lee et al., pages 27280-81).

Claim 1 further cannot be anticipated since Fenteany *et al.* and Lee *et al.* do not specifically disclose a peptide that specifically inhibits the interaction of an ubiquitin-proteasome segment with an ubiquitin-proteasome binding site comprising an amino acid sequence motif xEFIxxDx (SEQ ID NO:1), wherein D is aspartic acid, E is glutamic acid, F is phenylalanine, I is isoleucine and x is any other amino acid as recited in claim 1. In fact, Fenteany *et al.* and Lee *et al.* do not disclose any specific binding site to which a peptide binds. As stated by the Board of Patent Appeals and Interferences, a reference that "does not particularly or inherently describe the specifically claimed [] sequence ... cannot and does not anticipate the claimed [] sequence." (*Ex parte Loescher*, 2002 WL 31003050 (Bd. Pat. App. & Interf. 2002); (*See also*, *In re Duel*, 51 F.3d 1552, 1559-60, 34 USPQ2d 1210, Fed. Cir. 1995) (concluding that unless a cited reference specifically discloses the claimed sequence, the cited reference does not negate patentability)). Thus, claim 1 is novel.

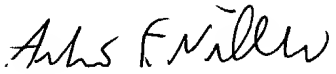
Claims 8 and 9 are not anticipated as depending from novel independent claim 1.

Accordingly, reconsideration and withdrawal of the anticipation rejections of claims 1 and 8-9 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, applicants submit that the claims define patentable subject matter and are in condition for allowance. If questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Andrew F. Nilles
Registration No. 47,825
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: March 26, 2004
AFN
Document in ProLaw